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86. (Amended) A method for desensitizing a subject against the occurrence of an allergic reaction in response to contact with an allergen, comprising administering to a subject an effective amount for desensitizing the subject against the occurrence of an allergic reaction of an immunostimulatory nucleic acid, wherein the immunostimulatory nucleic acid comprises a nucleotide sequence selected from the group of the following nucleotide sequences TCCATGTCGATCCTGATGCT (SEQ ID NO:36), TCCATGTCGGTCCTGATGCT (SEQ ID NO:28), and GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

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89. (Amended) The method of claim 86, wherein the immunostimulatory nucleic acid comprises the following nucleotide sequence GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

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REMARKS

Claims 42-101 are pending. Claim 54 has been cancelled herewith. Claims 56-59, 77, 79-82, 85-86 and 89 have been amended. No new matter has been added.

Allowable Subject Matter

Applicants respectfully thank the Examiner for the indication that the subject matter of pending claims 42, 43, 45-53, 55, 60-76, 78, 91, 93-95 and 97-101 is allowable over the prior art of record.

Amendment of the Claims

Applicants have amended Claims 56-59, 79-82, 85-86, and 89 to clarify the recitation of "sequence(s) including at least the following nucleotides". Claim 77 has been amended to clarify the recitation of "conventional adjuvant". Applicants submit, therefore, that each of the pending claims is now in condition for allowance.

Rejection of Claims 54, 56-59, 77 and 79-89 Under 35 USC §112

Claims 54, 56-59, 77 and 79-89 have been rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has listed several aspects of the claims which are indefinite. Applicants have amended claims 56-59, 77, 79-82, 85-86 and 89. It is believed that the Amendments to the claims are sufficient to overcome the rejection.

Applicants have amended claims 56, 58, 59, 80, 81, 85 and 89 to clarify the recitation of "sequence including at least the following nucleotides". These claims have been amended to define the immunostimulatory nucleic acid as comprising the nucleotide sequence as given in each claim, respectively. This amendment does not narrow the scope of the claims.

Applicants also have amended claims 57, 79, 82 and 86 to clarify the recitation of "sequences including at least the following nucleotides". The amendment of these claims makes it clear that the immunostimulatory nucleic acid of interest comprises a nucleotide sequence selected from the group of the nucleotide sequences as listed in the claims, respectively. Amendment of claims 82 and 86 are sufficient to overcome the objections to claims 83 and 87, respectively. The amendment does not narrow the scope of the claims.

Claim 77 has been amended to clarify the recitation of "conventional adjuvant". The use of "conventional" was unnecessary and was removed in order for the claim to refer to any adjuvant known to those skilled in the art. The amendment does not narrow the scope of the claims.

Claims 84 and 88 have been rejected for the use of "chimeric phosphodiester-phosphorothioate backbone" as being vague and indefinite. Applicants respectfully disagree. Applicants maintain that the term "chimeric phosphodiester-phosphorothioate backbone" is known and its meaning is understood by those of skill in the art. Additionally, the term is described in the Specification. The term "chimeric phosphodiester-phosphorothioate backbone" defines a backbone comprised of both phosphodiester and phosphorothioate internucleotide linkages. In the Specification the use of "chimeric" is shown to mean a modified backbone comprised of more than one type of internucleotide linkage, in this case phosphodiester and phosphorothioate linkages. Phosphate backbone modifications were

introduced on page 16 in the Specification. The Specification also teaches that preferably those modifications occur at the 5' end of the nucleic acid and/or the 3' end of the nucleic acid, with the center of the nucleic acid having a phosphodiester backbone. For instance, pages 33-34 describe chimeric backbones used for protecting the nucleic acid from degradation. The modifications described contained two 5' phosphorothioate-modified linkages and a variable number of 3' modified linkages. This sequence, described as containing central phosphodiester linkages with phosphorothioate linkages at the 5' and 3' ends, is an example of a chimeric ODN backbone with phosphodiester and phosphorothioate linkages. Other support for the term "chimeric" is found throughout the specification including Example 10 on page 62.

Claim 54 has been rejected because of the term "synthetic". It is Applicants belief that the term synthetic meets the requirements of §112, second paragraph. Claim 54, however, has been cancelled because it is not necessary. The nucleic acids of the invention include synthetically derived nucleic acids as well as naturally derived nucleic acids.

Rejection of Claims 44, 90, 92 and 96 Under 35 USC §103

Claims 44, 90, 92 and 96 have been rejected under 35 USC § 103(a) as being unpatentable over Kline et al (*J. Invest. Med.* 44(7) 380A, 1996).


A rejection in view of prior art may be overcome when the applicant is an author on the prior art publication and can assert that he is the sole inventor and that the other co-authors were working under the direction of the applicant. It is sufficient to present an affidavit or declaration by the applicant alone to demonstrate these facts, in order to remove the publication as a reference under 35 USC § 102(a). (MPEP § 715.01(c), citing *In re Katz*, 687 F2d 450, 215 USPQ 14(CCPA 1982).

Applicants submit herewith a Declaration of Dr. Joel Kline and Dr. Arthur Krieg under 37 CFR § 1.132. In the Declaration, Drs. Kline and Krieg establish that the Kline et al. reference (*J. Invest. Med.* 44(7): 380A, 1996) describes Drs. Kline's and Krieg's own work which led to this invention. Drs. Kline and Krieg have indicated in the attached Declaration that they are the sole inventors and that the remaining co-authors were merely working under their direction. The work described in the publication is their own invention.

SUMMARY

In view of the forgoing amendments and remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejections. This application should now be in condition for allowance. A Notice to the effect is respectfully requested. If the Examiner believes after this amendment that the application is not in condition for allowance, the Examiner is requested to call the Applicants' attorney at the number listed below.

Respectfully submitted,



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MARKED UP CLAIMS

56. (Amended) The method of claim 42, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence TCCATGACGTTCCCTGACGTT (SEQ ID NO. 10).

57. (Amended) The method of claim 42, wherein the immunostimulatory nucleic acid [has a sequence selected from the group of sequences including at least the following nucleotides] comprises a nucleotide sequence selected from the group of the following nucleotide sequences TCCATGTCGCTCCTGATGCT (SEQ ID NO:37), TCCATAACGTTCCCTGATGCT (SEQ ID NO:3), TCCATGACGATCCTGATGCT (SEQ ID NO:87), TCCATGACGTCCCTGATGCT (SEQ ID NO:39), TCCATGTCGTTCCCTGATGCT (SEQ ID NO:38), TCGTCGTTTTGTCGTTTTGTCGTT (SEQ ID NO:46), TCGTCGTTGTCGTTGTCGTT (SEQ ID NO:47), TCCATGACGGTCCTGATGCT (SEQ ID NO:35), TCCATGACGCTCCTGATGCT (SEQ ID NO:88), TCCATGACGTTCCCTGATGCT (SEQ ID NO:7), TCCATCACGTGCCTGATGCT (SEQ ID NO:40), TCGTCGTTGTCGTTTTGTCGTT (SEQ ID NO:49), GCGTGCGTTGTCGTTGTCGTT (SEQ ID NO:56), TGTCGTTTGTCGTTTGTCGTT (SEQ ID NO:48), TGTCGTTGTCGTTGTCGTT (SEQ ID NO:50), TCGTCGTCGTCGTT (SEQ ID NO:51), TCCTGTCGTTCCCTGTCGTT (SEQ ID NO:52), TCCTGTCGTTTTTTGTCGTT (SEQ ID NO:53), TCGTCGCTGTCTGCCCTTCTT (SEQ ID NO:54), and TCGTCGCTGTTGTCGTTTCTT (SEQ ID NO:55).

58. (Amended) The method of claim 42, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence TCCATGTCGCTCCTGATGCT (SEQ ID NO:37).

59. (Amended) The method of claim 42, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence TCGTCGTTTTGTCGTTTTGTCGTT (SEQ ID NO:46).

77.(Amended) The method of claim 60, further comprising administering [a conventional] an adjuvant.

79. (Amended) The method of claim 60, wherein the immunostimulatory nucleic acid [has a sequence selected from the group of sequences including at least the following nucleotides] comprises a nucleotide sequence selected from the group of the following nucleotide sequences TCCATGTCGCTCCTGATGCT (SEQ ID NO:37), TCCATAACGTTCTGATGCT (SEQ ID NO:3), TCCATGACGATCCTGATGCT (SEQ ID NO:87), TCCATGACGTCCCTGATGCT (SEQ ID NO:39), TCCATGTCGTTCTGATGCT (SEQ ID NO:38), TCGTCGTTTTGTCGTTTTGTCGTT (SEQ ID NO:46), TCGTCGTTGTCGTTGTCGTT (SEQ ID NO:47), TCCATGACGGTCCTGATGCT (SEQ ID NO:35), TCCATGACGCTCCTGATGCT (SEQ ID NO:88), TCCATGACGTTCCTGATGCT (SEQ ID NO:7), TCCATCACGTGCCTGATGCT (SEQ ID NO:40), TCGTCGTTGTCGTTTTGTCGTT (SEQ ID NO:49), GCGTGCGTTGTCGTTGTCGTT (SEQ ID NO:56), TGTCGTTTGTCGTTTGTCGTT (SEQ ID NO:48), TGTCGTTGTCGTTGTCGTT (SEQ ID NO:50), TCGTCGTCGTCGTT (SEQ ID NO:51), TCCTGTCGTTCTTGTCGTT (SEQ ID NO:52), TCCTGTCGTTTTTTGTCGTT (SEQ ID NO:53), TCGTCGCTGTCTGCCCTTCTT (SEQ ID NO:54), and TCGTCGCTGTTGTCGTTTCTT (SEQ ID NO:55).

80. (Amended) The method of claim 60, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence TCCATGTCGCTCCTGATGCT (SEQ ID NO:37).

81. (Amended) The method of claim 60, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence TCGTCGTTTTGTCGTTTTGTCGTT (SEQ ID NO:46).

82. (Amended) A method for treating asthma in a subject, comprising administering to an asthmatic subject an effective amount for treating asthma in a subject of an immunostimulatory nucleic acid, wherein the immunostimulatory nucleic acid[, has a sequence selected from the group of sequences including at least the following nucleotides] comprises a nucleotide sequence selected from the group of the following nucleotide sequences TCCATGTCGATCCTGATGCT (SEQ ID NO:36), TCCATGTCGGTCCTGATGCT (SEQ ID NO:28), and GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

85. (Amended) The method of claim 82, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

86. (Amended) A method for desensitizing a subject against the occurrence of an allergic reaction in response to contact with an allergen, comprising administering to a subject an effective amount for desensitizing the subject against the occurrence of an allergic reaction of an immunostimulatory nucleic acid, wherein the immunostimulatory nucleic acid[, has a sequence selected from the group of sequences including at least the following nucleotides] comprises a nucleotide sequence selected from the group of the following nucleotide sequences TCCATGTCGATCCTGATGCT (SEQ ID NO:36), TCCATGTCGGTCCTGATGCT (SEQ ID NO:28), and GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

89. (Amended) The method of claim 86, wherein the immunostimulatory nucleic acid [has a sequence including at least the following nucleotides] comprises the following nucleotide sequence GGGGTCAACGTTGAGGGGGG (SEQ ID NO:12).

